SECTION 5: 510(K) SUMMARY

Submitter:
Stryker Sustainability Solutions
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Tempe, Arizona 85283

DEC 2 0 2012

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Date of preparation: 29-JUN-2012

Name of device: Ultra ICE™ IntraCardiac Echo Catheter

Trade/Proprietary Name: Reprocessed Ultra ICE™ IntraCardiac Echo Catheter

Classification Name: Ultrasonic Pulsed Echo Imaging Catheter

Predicate Device	510(k) Title	Manufacturer
K980851	Galaxy Intravascular Ultrasound System	Boston Scientific

Device Description:
The Reprocessed Ultra IntraCardiac Echo Diagnostic Ultrasound Catheter is a 9F (3mm) diameter and 9 MHz frequency IntraCardiac Echocardiography Catheter which is 110cm in length.

The Ultra IntraCardiac Echo Catheter is constructed with an inner core and proximal connector. The catheter has a distal imaging window and an inserted rotatable imaging core with a distal ultrasound transducer.

The 9F (3mm)/9MHz Ultra IntraCardiac Echo Catheter can be used with the ClearView Ultra™ DSP system only after implementation of version 4.22 software or higher, or the Galaxy™ system.

Ultra IntraCardiac Echo Catheters rely on the rotational fidelity of the internal transducer and driveshaft assembly to accurately coincide with the position sensing electronics located in the Motordrive Unit (MDU). This arrangement is necessary in order to reduce the overall diameter of the catheter and to ensure that image information is displayed correctly on the screen. Although the transducer and driveshaft assembly is relatively rugged, its performance depends on free rotation of the shaft within the catheter body. Pinching, crushing, and extremely sharp bends are to be avoided during use and handling.

Although the catheter body will adequately protect and guide the internal rotating assembly, care should be taken so that the catheter body is not abraded, cut or used to pull the motor

assembly into position. The catheter body is formed at its distal tip so that the ultrasound energy is efficiently emitted and received. Design and functional constraints require that the distal tip be less strong, rendering it more susceptible to crushing and bending than the proximal portions. For this reason, it is strongly recommended that the tip be carefully inspected visually prior to use and after removal.

Indications for Use:
The Reprocessed Ultra IntraCardiac Echo Diagnostic Ultrasound rounded tip catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.

Technological Characteristics:
The design, materials, and intended use of Reprocessed Ultra IntraCardiac Echo Catheter are identical to the predicate devices. The mechanism of action of the reprocessed device is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of Ultra ICE™ IntraCardiac Echo Catheter includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations

Performance data:
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Ultra ICE™ IntraCardiac Echo Catheter. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Ultra ICE™ IntraCardiac Echo Catheter perform as originally intended.

Conclusion:
Stryker Sustainability Solutions concludes that the modified devices (Reprocessed Ultra ICE™ IntraCardiac Echo Catheter) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 2 0 2012

Stryker Sustainability Solutions
c/o: Moira Barton-Varty
Senior Director Regulatory Affairs
1810 W Drake Dr
Tempe, Arizona 85283

Re: K121913
Trade Name: Reprocessed Ultra IntraCardiac Echo Diagnostic Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: November 18, 2012
Received: November 19, 2012

Dear Ms. Barton-Varty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121913

Device Name: Reprocessed Ultra IntraCardiac Echo Diagnostic Ultrasound Catheter

Indications For Use: The Reprocessed Ultra IntraCardiac Echo Diagnostic Ultrasound rounded tip catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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